

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Masashi ISOZAKI et al.) Group Art Unit: 1633
Application No.: 10/594,427) Examiner: Fereydoun SAJJADI
Filed: September 26, 2006) Confirmation No.: 2940
For: LIPOSOME PREPARATION)

RESPONSE TO RESTRICTION AND ELECTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In complete response to the Restriction and Election Requirement dated November 20, 2009, Applicants submit herewith the following response. This paper is timely filed on December 22, 2009 because December 20, 2009 was a Sunday and the United States Patent and Trademark Office was closed on December 21, 2009.

The Examiner has required restriction to one of the following three Groups:

Group I: Claims 1-17, drawn to a liposome preparation comprising a lipid bilayer comprising a phospholipid, an interior aqueous phase with a pH of up to 5, a drug and a hydrophilic macromolecule;

Group II: Claim 18, drawn to a method of producing a liposome preparation comprising preparing a vesicle lipid bilayer comprising a phospholipid, and interior aqueous phase with a pH of up to 5, adding a lipid derivation of a hydrophilic macromolecule, and encapsulating a drug in the interior aqueous phase, during vesicle preparation; and

Group III: Claim 18, drawn to a method of producing a liposome preparation comprising preparing a vesicle lipid bilayer comprising a phospholipid, and interior aqueous phase with a pH of up to 5, adding a lipid derivation of a hydrophilic macromolecule, and encapsulating a drug in the interior aqueous phase by adding the drug from the exterior of the

vesicle after preparing the vesicle by penetration through the lipid layer.

Applicants hereby provisionally elect Group I, Claims 1-17, drawn to a liposome preparation comprising a lipid bilayer comprising a phospholipid, an interior aqueous phase with a pH of up to 5, a drug and a hydrophilic macromolecule.

In addition, the Examiner has required election of species from among each of the following generic groupings:

- a. Various species of phospholipids, as disclosed on pages 14-15 of the specification;
- b. Various hydrophilic macromolecules, as disclosed on pages 14-15 of the specification; and
- c. Various drugs, as disclosed on pages 29-31 of the specification.

Applicants hereby elect with traverse:

- a. Phospholipid: phosphatidylcholine;
- b. Hydrophilic macromolecule: polyethylene glycol; and
- c. Drug: doxorubicin hydrochloride.

The restriction requirement is traversed. A special technical feature shared by the invention recited in the claims is the structure of the liposome vehicle. For example, the choice of drug is not related to this special technical feature and the claims are generic as to the elected species. A special technical feature shared by the drugs listed in ¶ [0046] is that these drugs are stable at the pH of the liposome structured as recited in claim 1. It is understood that upon allowance of a generic claim, applicants are entitled to examination of a reasonable number of species.

This election is made without prejudice to or disclaimer of any non-elected subject matter. It is understood that in the event that a generic claim is found allowable, the Applicant will be entitled to examination of a reasonable number of

additional species pursuant to 37 C.F.R. § 1.141 and as set forth in the Office Action at page 6. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any non-elected subject matter.

Further favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited. In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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